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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,961	06/04/2001	Puranam U. Sarma	2761-0147P	5257

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/871,961	SARMA ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-61* is/are pending in the application.

4a) Of the above claim(s) *44-47,58,60 and 61* is/are withdrawn from consideration.

5)☒ Claim(s) *42, 43, 48-57, and 59* is/are allowed.

6)☒ Claim(s) *35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 February 2004 has been entered.

Claims 35-61 are pending. This application contains claims 44-47, 58, 60, and 61 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

As Applicants have provided no amendments to the claims, thus all rejections have been maintained and re-iterated below for Applicant's convenience and this action is made final.

Declaration

The declaration filed 3 February 2004 has been considered however is not persuasive. The declaration is not commensurate in scope with the **rejected** claims. The declaration provides a background of the inventor, as well as a background of the invention and the state of the art including an explanation of the well-known technology of enzyme linked immunosorbant assays (ELISA). While it is agreed that one could have practiced the method without undue experimentation for the embodiments in which the antibody binds to the epitopes defined by SEQ ID NOS: 1-6, the claims are not so limited. The use of "comprising" in the claim language represents open claim language. As such, there is a lack of limitations in the claims to describe to which epitope the antibodies must bind. The claims embrace **any** peptide containing the

recited subsequences, even if they are unrelated to *Aspergillosis*. It is noted that claims 42, 43, 48-57, and 59 reciting "amino acids consisting of" have been indicated as allowable.

It appears from the declaration and the arguments that Applicant is unclear about the Examiner's position regarding the rejections set forth over claims reciting "comprising". Please see the enablement rejection below for clarification.

Claim Rejections - 35 USC § 112

Claims 35-41 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to diagnose aspergillosis based upon the amount of peptide IgG/IgE complexes and correlate absorbance values with acuteness of aspergillosis using the specific epitopes of SEQ ID NOS: 1-6. For the reasons discussed below, this would constitute undue experimentation.

b) The specification provides little or no guidance to enable the practice of said invention using an amino acid sequence **comprising** one of SEQ ID NOS: 1-6. The specification only provides enablement of using an amino acid sequence **consisting** of SEQ ID NOS: 1-6.

c) The specification shows in Table 2 that the instant invention is enabled for the exact sequences 1-6, however, it does not enable or show that any other peptide sequence which contains SEQ ID NOS: 1-6 would work. For example, the specific eptiopes of SEQ ID NOS: 1-6 are bound to an ELISA plate for antibody recognition. If the epitope were altered, for example, by addition of one or more amino acids, it may not be recognized by the antibodies such that the invention would be enabled. The addition of even a single amino acid, as is well known in the art, could severley alter the peptide such that it folds in an alternate way, in effect "hiding" the epitope from antibody recognition. Thus, an amino acid **comprising** one of SEQ ID NOS: 1-6 encompasses additional amino acids, other than the specific recited amino acids.

d) The invention is drawn to methods of diagnosing aspergillosis using ELISA with peptides **comprising** a sequence consisting of SEQ ID NOS: 1-6.

e) While the prior art does contain references to ELISA plates as useful to confirm a diagnosis, as in the case of Lyme disease, no comparable methods for have been established for using a peptide other than exact known peptides that make up a certain epitope to be recognized.

f) The skill of those in the art of molecular biology is high, however there is no guidance in the specification that would enable even a skilled practitioner to practice the said invention without undue experimentation in order to test a variety of peptides **comprising** SEQ ID NOS: 1-6.

g) There is no way a priori of indicating that any other sequence would be enabled, given no guidance in the prior art and given the fact that the prior art teaches that altering amino acid sequence may effect tertiary structure.

h) The claims are broad because they are drawn to epitopes that are not defined in the specification or the prior art for peptides other than the exact peptides of SEQ ID NOS: 1-6. The above specification would lead one to practice undue experimentation in order to practice the said invention.

Claims 35-41 are not allowed. Claims 42, 43, 48-57, and 59 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

March 4, 2004
Lori A. Clow, Ph.D.
Art Unit 1631

MARJORIE MORAN
PATENT EXAMINER